U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology



Public Health Case Reporting Prototype Use Case August 31st, 2007



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1.0 Preface

Use cases developed for the American Health Information Community (AHIC) are based on the priorities expressed by the AHIC workgroups. These high-level use cases focus on the needs of many individuals, organizations, and systems rather than the development of a specific software system. The use cases describe involved stakeholders, information flows, issues, and systems needs that apply to the multiple participants in these arenas.

The use cases strive to provide enough detail and context for detailed policy discussions, standards harmonization, certification considerations, and architecture specifications necessary to advance the national health information technology (HIT) agenda. These high-level use cases focus, to a significant degree, on the exchange of information between organizations and systems rather than the internal activities of a particular organization or system.

During the January 2007 AHIC meeting, nine priority areas (representing over 200 identified AHIC and AHIC workgroup detailed priorities) were discussed and considered. Three of these areas (Consumer Access to Clinical Information, Medication Management, and Quality) were prioritized and developed into the 2007 Detailed Use Cases, which were published in June 2007. The Health Information Technology Standards Panel (HITSP) Technical Committees are currently conducting harmonization work on these use cases.

The remaining six priority areas from the January 2007 AHIC meeting were updated based upon AHIC feedback and were reviewed during the July 2007 AHIC meeting. These six priority areas are now being developed into the 2008 Use Cases (Remote Monitoring, Remote Consultation, Personalized Healthcare, Consultation and Transfers of Care, Public Health Case Reporting, and Immunizations & Response Management) which will be processed in the national HIT agenda activities in 2008.

The 2008 Use Cases are being developed by the Office of the National Coordinator for Health Information Technology (ONC) with opportunities for review and feedback by interested stakeholders within both the private and public sectors. To facilitate this process, the use cases are being developed in two stages:

- The **Prototype Use Cases** describe the candidate workflows for the use case at a high level, and facilitate initial discussion with stakeholders; and
- The **Detailed Use Cases** document all of the events and actions within the use case at a detailed level.

This document is a prototype use case, which describes at a high level the actors, capabilities, and information sharing needs associated with this use case. ONC is publishing the prototype use case at an earlier stage of development in order to incorporate more substantive input from interested stakeholders into the detailed use case.



The prototype use case is divided into the following sections:

- Section 2.0, Introduction and Scope, briefly describes the priority needs identified by one or more AHIC workgroups and preliminary decisions made about the scope of the use case.
- Section 3.0, Use Case Stakeholders, briefly describes individuals and organizations which participate in activities related to the use case and its components.
- Section 4.0, Issues and Obstacles, briefly describes issues or obstacles which
 may need to be resolved in order to achieve the capabilities described in the use
 case.
- Section 5.0, Perspectives, briefly describes how the use case combines similar roles (or actors) in order to describe their common needs and activities. The roles are intended to describe functional roles rather than organizations or physical entities.
- Section 6.0, Candidate Workflows, briefly describes how various perspectives interact and exchange information within the context of a workflow. The use case workflow model provides a context for understanding the information needs and is not meant to be prescriptive.
- Appendix A, the Glossary, provides draft definitions of key concepts and terms contained in the prototype.

Also within the prototype document are specific questions for which ONC would like to receive feedback during the development process. Following receipt of feedback from interested stakeholders, ONC will develop a detailed use case, which will incorporate the feedback received, fully describe the events and activities from a variety of perspectives, and include information flow diagrams.



2.0 Introduction and Scope

In January 2007, AHIC approved a recommendation to develop a use case addressing population health as it applies to public health case reporting and some aspects of adverse event reporting.

Population health could be enhanced through electronic public health case and adverse event reporting to local, state, federal, and other public health entities. Electronically supported epidemiology in support of population health can be advanced by integration of public health systems with Electronic Health Records (EHRs) and Laboratory Information Systems (LISs) and bi-directional communication between providers and public health entities. Leveraging electronic clinical information to address population health data requirements, providers may have access to population health decision support, and have the ability to be alerted to and report notifiable conditions and events as determined by predetermined case definitions, adverse events such as those associated with medications, vaccinations, etc., and other population health concerns.

In specific terms:

- Providers and laboratories will benefit from having the ability to integrate laboratory results, pre-determined case definitions, automated case reporting mechanisms, and electronic forms into EHR systems and LISs.
- Providers and public health will benefit from having the ability to automate the process to prompt a provider of the need to report a possible and/or confirmed public health case and/or adverse event, based on the presence of clinical data in the EHR, LIS, or potentially other sources of information, pre-populate reports with available data, prompt clinicians and clinical personnel to provide necessary additional information and thereby automating the reporting process from the provider to the public health entity.
- Providers and public health will benefit from having the ability to electronically exchange possible and confirmed cases and events as wells as population health information between EHR systems and Public Health systems.
- Providers will benefit from integration with decision support in determining possible events/cases, identifying a case/event and prompting clinicians to approve notifiable condition reports and/or adverse event reports.

One of the goals of AHIC is establishing a pathway, based on common data standards, to facilitate the incorporation of interoperable, predetermined case definitions and event reporting specifications into EHRs and/or other tools to support the defining of cases and other clinical decision-making efforts. This use case was developed to support the various stakeholders who are active in the development and implementation of electronic health



records and health information exchange (HIE) including those engaged in activities related to standards, interoperability, harmonization, architecture, policy development, and certification. To support this, the Public Health Case Reporting Prototype Use Case focuses on the exchange of population health information between laboratories, providers, and public health and describes two candidate workflows:

- Reporting and Data Sharing. Pre-determined public health case definitions and adverse event reporting specifications are utilized by providers and laboratories in the reporting of possible and/or confirmed cases/events. Population health information exchange and provider-to-provider communication may also occur, assisting providers in understanding the context of the case/event.
- Investigation. Various types of information, including additional case/event information are utilized by public health to confirm cases/events, develop and/or refine the case definition or event identification criteria, and estimate the potential impact.

There are associations between the candidate workflows in this use case and the candidate workflows in the 2008 Immunizations & Response Management Prototype Use Case.

This use case assumes the developing presence of electronic systems such as EHRs, LISs and other local or Web-based solutions supporting providers, laboratories, and public health while recognizing the issues and obstacles associated with these assumptions. This approach helps promote the development of longer-term efforts.



3.0 Use Case Stakeholders

Figure 3-1. Public Health Case Reporting Use Case Stakeholders Table

Stakeholder	Working Definition
Ancillary Entities	Organizations that perform auxiliary roles in delivering healthcare services. They may include diagnostic and support services such as laboratories, imaging and radiology services, and pharmacies that support the delivery of healthcare services. These services may be delivered through hospitals or through freestanding entities.
Government Agencies	A department of a local, state, or national government responsible for the oversight and administration of a specific function. Government agencies that could participate in Public Health Case Reporting may include: Food & Drug Administration (FDA), Centers for Disease Control (CDC), Centers for Medicare & Medicaid (CMS), Department of Defense (DoD), Department of Homeland Security (DHS), etc.
Healthcare Entities	Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health, school health, dental clinics, psychology clinics, care delivery organizations, and other healthcare facilities.
Healthcare Payors	Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations.
Knowledge Providers	Associations of public health individuals/organizations who provide technical advice and assistance to state and local health agencies in a broad range of areas including: occupational health, infectious diseases, immunization, environmental health, chronic diseases, injury control, and maternal and child health.
Laboratories	A laboratory (often abbreviated as lab) is a setting where scientific research and experiments are conducted. Laboratories may have specific functionality and may work with veterinarian/animal, environmental, human, other specimens.
Manufacturers/Distributors	Entities which may be involved in the following activities: research, development, testing, production, storage, distribution, surveillance, and communication regarding medical/healthcare products at the community, regional, and national level, such as pharmaceutical manufacturers, drug wholesalers, medical device suppliers, etc.
Patients	Members of the public who receive healthcare services.
Providers	Clinicians within healthcare delivery organizations, or the organizations themselves, with patient interaction in the delivery of care including physicians, nurses, and other clinicians. Can also refer to healthcare delivery organizations. Healthcare delivery may also occur in settings such as: schools, correctional institutions, research settings, etc.
Public Health Agencies (local/state/federal)	Local, state, and federal government organizations and personnel that exist to help protect and improve the health of their respective constituents.
Reporting Entities	Organizations that report possible and/or confirmed (within their organization) cases/events to public health.



Stakeholder	Working Definition
Research Entities	Organizations that are engaged in or support healthcare research. These entities could include those performing clinical trials, National Institutes of Health (NIH), etc.
Response Management Entities	Organizations that are responsible for the emergency evaluation and response to natural disasters. i.e Federal Emergency Management Agency (FEMA), Red Cross, etc.

ONC would like to receive feedback on the draft list of stakeholders and their descriptions for this use case. Please suggest additions, deletions and/or revisions to the description of the stakeholders.



4.0 Issues and Obstacles

Realizing the full benefits of automated public health case and adverse event reporting will be dependent on overcoming a number of issues and obstacles in today's environment. Inherent in this use case is the premise that some of these will addressed through HIT standardization and harmonization activities, policy development, HIE networks and other related initiatives.

Electronic case/event reporting and population health information exchange can provide valuable information to public health and providers of care. This information may be provided more readily than available today. Some of the issues raised and challenges regarding case reporting and population HIE are listed below.

Confidentiality, Privacy, Security and Data Access

- Patient data confidentiality and privacy
 - o Consistent approaches for supporting patient confidentially wherever possible are needed. Such protections must balance reporting mandated by state law and the needs to support authorized public health investigation.
 - Procedures and agreements that support data exchange (including privacy protections to prevent confidentiality breaches or misuses) and secondary data uses need to be developed and executed.

Information Interoperability and Exchange

- Today, public health case and adverse event reporting is typically accomplished via the submission of a report communicating the presence of a notifiable condition by paper, phone or fax to public health.
 - o Healthcare facilities' (i.e., hospitals, clinics, laboratories, ancillary clinical facilities) may not have the ability to electronically collect, process, and transmit pertinent public health data in a secure fashion and timely fashion.
 - Feedback loops/processes which inform the reporting entities of the results of their reported cases/events often do not exist today. Network and policy infrastructures to enable secure, consistent, appropriate, reliable, and accurate information exchange will need to be established.
 - Efforts to minimize duplicative reporting are needed. For example, if a
 physician orders a lab test for a patient, it is desirable to determine that
 independent reports by the physician and lab are referring to the same case.



Consistent method(s) for data categorization, dynamic cast definition and specific criteria for sharing data of public health significance are needed. Upon criteria development, information exchange between providers and/or cross jurisdictional public health departments will also need to be addressed.

Decision Support

Decision support can have potentially dramatic results in public health case reporting, however, there are limited options available today, and a lack of standardization in these systems. Specific issues include:

- Reporting requirements vary at the local, state, and federal level. There are limited and varied algorithms for detecting possible cases/events.
- Fragmented databases with no standardized data structure to populate EHRs, etc.

ONC would like to receive feedback on the draft list of issues and obstacles and their descriptions for this use case. Please suggest additions, deletions and/or revisions.



5.0 Use Case Perspectives

The Public Health Case Reporting Prototype Use Case focuses on the exchange of population health information to support the reporting and management of possible and confirmed public health cases and adverse events. The use case will describe public health case reporting from the viewpoint associated with three perspectives. The perspectives included in the use case are intended to indicate roles and functions, rather than physical locations. Each is perspective is described below:

Provider

The provider perspective includes clinicians which may be practicing in various settings, such as: office practices, research entities, manufacturers/distributors, healthcare delivery organizations, correctional institutions, schools, public health entities, etc. Providers may report possible cases and/or events to public health. Providers may also report cases and/or events which they have confirmed within their setting(s) to public health.

Laboratory

The laboratory perspective includes various laboratories, such as public health laboratories, private laboratories, and even environmental laboratories and laboratories which receive veterinary specimens, etc. Laboratories may report possible cases and/or events to providers and/or public health based on specific lab results generated for clinical purposes. They also play an important role in confirming possible cases identified to them by public health or clinical care personnel during an investigation.

Public Health

The public health perspective includes infection control at the facility/organization level, local, state, federal public health departments, agencies, or others that may assist and/or operate in a public health capacity. Public health receives cases and events which have been categorized as "possible" or "confirmed" by the reporting entities, including public health, providers and laboratories. Public health confirms or refutes the cases or events, accesses various information through investigations and may provide public health information to the provider and/or laboratory perspectives.

Public Health Case Reporting Prototype Use Case



These perspectives are the focus of the events described in the following candidate workflows.

ONC would like to receive feedback on the draft list of perspectives and their descriptions for this use case. Please suggest additions, deletions and/or revisions.



6.0 Candidate Workflows

The Public Health Case Reporting Prototype Use Case focuses on the exchange of population health information as well as the reporting of possible and confirmed public health cases and adverse events which is described in the two candidate workflows.

There are associations between the candidate workflows in this use case and the candidate workflows in the 2008 Immunizations & Response Management Use Case.

6.1 Reporting and Data Sharing

This candidate workflow is focused on incorporating pre-determined case definitions, event-level reporting specifications into EHRs, LISs, and other tools which are utilized by providers and laboratories in the reporting of possible and/or confirmed cases/events. Population-level data exchange between providers and Public Health and providers and other providers may also occur, assisting providers in understanding the context of the environment.

- Providers and laboratories receive and incorporate pre-determined case definitions and reporting criteria.
 - Pre-determined case definitions and reporting and exchange criteria may be available from local, state, and federal public health entities. These entities may include government agencies, knowledge providers, or other entities performing in a public health role.
 - The definitions and criteria may be incorporated into the EHR and/or an LIS.
- Providers and laboratories filter EHR or LIS data for information matching inclusion/exclusion factors
 - Laboratories may identify information matching inclusion factors and may exchange this information not only with public health but also with the ordering entity and/or the provider of the specimen.
 - o Providers may identify information matching inclusion factors and will prepare to exchange this information with public health.
- Providers augment, validate, and report information required for reporting of possible and/or confirmed cases/events.
 - Providers may utilize information from various sources, including laboratories.



- Reporting information is exchanged with public health. Information exchange may also occur between providers.
 - This type of level of information exchanged may be based upon pre-determined agreements which comply with local, state, federal or other applicable regulations.
- Public health electronically receives case/event report information from the reporting entities (providers and laboratories).
 - Public health may acknowledge receipt and communicate this receipt to the reporting entities.
 - Public health may also request clarification and/or additional information from the reporting entities.
- Providers and laboratories may receive related or other population health information from public health.
 - o While preferable, providers and laboratories may not receive direct communication in regards to the status of their submitted reports.
 - Providers, laboratories, etc. may receive varying degrees of population health information from public health.
 - Population health information may or may not be incorporated into the mechanisms such as the EHR, LIS, etc.
 - This information exchange may be triggered by information gained from Candidate Workflow 2: Investigation.
- Providers and Laboratories may utilize additional information and report additional cases/events.
 - Providers and laboratories may re-address their inclusion/exclusion factors based upon updated and/or additional information.

6.2 Investigation

This candidate workflow is focused on the ability for public health to access and analyze information to determine whether or not cases/events can be confirmed, the case definition and/or event detection criteria updated, and the potential spread and impact.

 Public health accesses and analyzes additional information from reporting entities (providers and laboratories).



- Information provided by reporting entities may also include information from providers in other settings.
- Public health may also access information from other public health entities.
 This information may be accessed on a routine or emergency basis, based upon jurisdictional agreements.
 - The information which is shared may be summarized or have a limited view.
- Public health confirms or refutes case/event.
 - During this process the case/event, if the public health case definition or adverse event detection criteria was not already determined it may now be developed, refined and communicated.
- Public health initiates information exchange and may continue exchanging population health information.
 - As discussed in Candidate Workflow 1: Reporting and Data Sharing, public health may provide reporting and possibly other entities with varying degrees of population health information which may assist providers in understanding the context of their environment.

ONC would like to receive feedback on the public health case reporting in regards to what types and/or levels of public health information could ideally be exchanged on a routine and/or emergency basis?

- Public health performs investigations, including epidemiologic investigations, contact tracing, etc. to determine potential population health impact.
 - Requesting clarification or additional information from reporting entities and affected individuals may assist public health in performing these investigations.
 - Receiving additional possible and/or confirmed case/event information from reporting entities may also assist public health in performing these investigations.
- Public health may provide guidance on prevention or treatment intervention administration.



Prevention and treatment intervention administration is discussed in the 2008
 Immunizations & Response Management Use Case.

ONC would like to receive feedback on the candidate workflows. Should any changes be made to the descriptions of these interactions? For those candidate workflows listed, is the working definition of key information sources and recipients sufficient? If not, what changes should be made?



Appendix A: Glossary

Adverse Event (Event): Is any adverse change in health or "side-effect" that occurs in a person during a clinical trial or during health related circumstances. Adverse events may be related to and declared in regards to drugs, vaccinations, devices, procedures, patient care, etc.

AHIC: American Health Information Community.

Ancillary Entities: Organizations that perform auxiliary roles in delivering healthcare services. They may include diagnostic and support services such as laboratories, imaging and radiology services, and pharmacies that support the delivery of healthcare services. These services may be delivered through hospitals or through free-standing entities.

CDC: Centers for Disease Control & Prevention, a federal agency within the Department of Health and Human Services.

Clinicians: Healthcare providers with patient care responsibilities, including physicians, advanced practice nurses, physician assistants, nurses, and other credentialed personnel involved in treating patients.

CMS: Centers for Medicare & Medicaid Services, a federal agency within the Department of Health and Human Services.

Consumers: Members of the public who may receive healthcare services. These individuals may include: caregivers, patient advocates, surrogates, family members, and other parties who may be acting for, or in support of, a patient in the activities of receiving healthcare.

Department of Health and Human Services (HHS): This is the federal agency responsible for human health, and has oversight over many other federal agencies such as FDA, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), CMS, the Agency for Health Research and Quality (AHRQ), the Substance Abuse and Mental Health Services Administration (SAMHSA), and others.

Electronic Health Record (EHR): The electronic health record is a longitudinal electronic record of patient health information generated in one or more encounters in any care delivery setting. This information may include patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory information and radiology reports.



FDA: Food and Drug Administration.

Government Agencies: A department of a local, state, or national government responsible for the oversight and administration of a specific function. Government agencies that could participate in Public Health Case Reporting may include: Food & Drug Administration (FDA), Centers for Disease Control (CDC), Centers for Medicare & Medicaid (CMS), Department of Defense (DoD), Department of Homeland Security (DHS), etc.

Health Information Exchange (HIE): A multi-stakeholder entity that enables the movement of health-related data within state, regional, or non-jurisdictional participant groups.

Healthcare Entities: Organizations that are engaged in or support the delivery of healthcare. These organizations could include hospitals, ambulatory clinics, long-term care facilities, community-based healthcare organizations, employers/occupational health, school health, dental clinics, psychology clinics, care delivery organizations, and other healthcare facilities.

Healthcare Payors: Insurers, including health plans, self-insured employer plans, and third party administrators, providing healthcare benefits to enrolled members and reimbursing provider organizations.

HITSP: Healthcare Information Technology Standards Panel.

Knowledge Providers: Associations of public health individuals/organizations who provide technical advice and assistance to state and local health agencies in a broad range of areas including: occupational health, infectious diseases, immunization, environmental health, chronic diseases, injury control, and maternal and child health.

Laboratories: A laboratory (often abbreviated lab) is a place where scientific research and experiments are conducted. Laboratories may be specific and may work with veterinarian/animal, environmental, human, other specimens.

Manufacturers/Distributors: Entities which may be involved in the following activities: research, development, testing, production, storage, distribution, surveillance, and communication regarding medical/healthcare products at the community, regional, and national level, such as pharmaceutical manufacturers, drug wholesalers, medical device suppliers, etc.

ONC: Office of National Coordinator for Health Information Technology.

Patients: Members of the public who receive healthcare services.



Point-to-Point Exchange: A direct link or communication connection with defined endpoints.

Providers: Clinicians within healthcare delivery organizations, or the organizations themselves, with patient interaction in the delivery of care including physicians, nurses, and other clinicians. Can also refer to healthcare delivery organizations. Healthcare delivery may also occur in settings such as: schools, correctional institutions, research settings, etc.

Public Health Agencies (local/state/federal): Local, state, and federal government organizations and personnel that exist to help protect and improve the health of their respective constituents.

Public Health Case (case): Is when a possible or confirmed notifiable disease/condition has been detected. In some circumstances the disease/condition may not be predetermined and therefore, may not initially fall into the notifiable category. Requirements for reporting disease/conditions may be different and may be mandated by local, state, federal laws or regulations.

Research Entities: Organizations that are engaged in or support healthcare research. These entities could include those performing clinical trials, NIH, etc.

Reporting Entities: Organizations that report possible and/or confirmed (within their organization) cases/events to public health.

Response Management Organizations: Organizations that are responsible for the emergency evaluation and response to natural disasters. i.e. - Federal Emergency Management Agency (FEMA), Red Cross, etc.